

Food and Drug Administration, HHS

§ 520.2473b

Brachyspira hyodysenteriae susceptible to tiamulin.

(ii) *Limitations.* Use for 5 consecutive days. Withdraw 3 days before slaughter. Prepare fresh water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water.

(2) *Amount.* 10.5 milligrams of tiamulin per pound of body weight for 5 days.

(i) *Indications for use.* For treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(ii) *Limitations.* Use for 5 consecutive days. Withdraw 7 days before slaughter. Prepare fresh water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin or salinomycin) as adverse reactions may occur.

[52 FR 15718, Apr. 30, 1987, as amended at 58 FR 14313, Mar. 17, 1993; 62 FR 35076, June 30, 1997; 70 FR 13099, Mar. 18, 2005]

§ 520.2456 Tiamulin liquid concentrate.

(a) *Specifications.* A liquid concentrate containing 12.3 percent tiamulin used to make a medicated drinking water containing 227 milligrams or 681 milligrams of tiamulin per gallon.

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.738 of this chapter.

(d) *Conditions of use in swine—* (1) *Amount.* Dysentery: 3.5 milligrams of tiamulin per pound of body weight daily. Pneumonia: 10.5 milligrams of tiamulin per pound of body weight daily.

(2) *Indications for use.* For treatment of swine dysentery associated with *Treponema hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(3) *Limitations.* Use for 5 consecutive days. When a dose is 3.5 milligrams per pound of body weight daily, withdraw medication 3 days before slaughter. When a dose is 10.5 milligrams per pound of body weight daily, withdraw 7 days before slaughter. Prepare fresh

medicated water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, or salinomycin) as adverse reactions may occur.

[58 FR 14313, Mar. 17, 1993, as amended at 62 FR 35076, June 30, 1997]

§ 520.2473 Tioxidazole oral dosage forms.

§ 520.2473a Tioxidazole granules.

(a) *Specifications.* Each gram of granules contains 200 milligrams of tioxidazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Horses—*(i) *Amount.* 5 milligrams per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.)

(iii) *Limitations.* For administration with feed: Sprinkle required amount of granules on a small amount of the usual grain ration and mix. Prepare for each horse individually. Withholding of feed or water not necessary. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[50 FR 52772, Dec. 26, 1985; 51 FR 2693, Jan. 21, 1986, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.2473b Tioxidazole paste.

(a) *Specifications.* Each plastic syringe contains 6.25 grams of tioxidazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Horses—*(i) *Amount.* 5 milligrams of tioxidazole per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* Administer orally by inserting the nozzle of the syringe through the space between front and back teeth and deposit the required dose on the base of the tongue. Before dosing, make sure the horse's mouth contains no feed. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[52 FR 43059, Nov. 9, 1987]

§ 520.2481 Triamcinolone acetonide tablets.

(a) *Specifications.* Each tablet contains either 0.5 milligram or 1.5 milligrams of the drug.

(b) *Sponsor.* See Nos. 000010 and 053501 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use.* (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.

(2) An initial daily dosage of 0.05 milligram per pound of body weight is usually sufficient to control symptoms, although up to 0.1 milligram per pound of body weight may be given daily if response to the smaller dose is inadequate. As soon as feasible, and in any case within 2 weeks, dosage should be reduced gradually to maintenance levels of 0.0125 to 0.025 milligram per pound of body weight per day. Therapy should be discontinued by a gradual reduction in dosage after the condition has been controlled for several days. Therapy may be initiated with a single

dose of sterile triamcinolone acetonide suspension veterinary in which case the tablet dosage should be administered beginning 5 to 7 days after the injection or when symptoms reappear.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 51 FR 26002, July 18, 1986; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.2482 Triamcinolone acetonide oral powder.

(a) *Specifications.* Each 15 grams of triamcinolone acetonide oral powder contains 10 milligrams of triamcinolone acetonide.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use.* (1) The drug is used as an anti-inflammatory agent for horses.

(2) It is administered at a dosage of 0.005 to 0.01 milligram triamcinolone acetonide per pound of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Treatment may be initiated with a single dose of sterile triamcinolone acetonide suspension USP followed after 3 or 4 days with the use of triamcinolone acetonide oral powder.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 24884, June 21, 1976, as amended at 50 FR 41489, Oct. 11, 1985; 51 FR 26002, July 18, 1986]